

DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE WASHINGTON DC



20 August 2007

MEMORANDUM FOR ALMAJCOM/SG

FROM: HQ USAF/SG3

110 Luke Avenue, Room 400 Bolling AFB DC 20032-7050

SUBJECT: Air Force 2007-2008 Influenza Immunization Program Guidance

This memo and attached guidance provide implementation instructions for 2007-08 influenza immunization programs, supplementing AFJI 48-110, Immunizations and Chemoprophylaxis.

Air Force medical staff will administer influenza vaccines to all military members in accordance with AFJI 48-110 and offer vaccines to eligible beneficiaries as appropriate. The success of this year's influenza immunization program will require maximum use of the live, attenuated, intranasal vaccine, FluMist® whenever possible and reservation of FluZone® products exclusively for pediatric patients. MTF staff must ensure vaccination of all mission-critical military personnel and high-risk beneficiaries.

Immunization personnel and healthcare providers should review the most recent Advisory Committee on Immunization Practices (ACIP) recommendations on prevention and control of influenza for updates and changes. MTF leadership should work to improve vaccination coverage and remove barriers to influenza vaccination.

While maintaining the high level of influenza vaccine coverage previously achieved for military members, medical staff and commanders should develop programs to target beneficiaries who are at increased risk for influenza-related complications.

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Attachment:

Influenza Immunization Program Guidance

Air Force 2007-2008 Influenza Immunization Program Guidance

1) **Purpose:** This message provides Air Force guidance for influenza vaccination programs. Request dissemination of this message to all military treatment facilities (MTFs), MTF/CC's, immunization point of service/clinics, public health offices, pharmacy services, medical logistic/supply sections, and primary care managers.

2) Influenza

- a) Seasonal influenza epidemics occur annually in the United States. Estimates of influenza-related events include 95 million infections, 25 million physician visits, 200,000 hospitalizations, and 36,000 deaths annually in the United States.
- b) Immunization is the key to seasonal influenza prevention.

3) Virus Vaccines and Their Availability:

- a) Both the inactivated and live, attenuated vaccines prepared for the 2007—2008 season will include A/Solomon Islands/3/2006 (H1N1)-like, A/Wisconsin/67/2005 (H3N2)-like, and B/Malaysia/2506/2004-like antigens. Influenza viruses for both TIV and LAIV are grown in embyonated chicken eggs, and, therefore, might contain limited amounts of residual egg protein. Therefore, persons with a history of severe hypersensitivity, such as anaphylaxis, to eggs should not receive influenza vaccine.
- b) DoD-contracted manufacturers for 2007-08 are Sanofi Pasteur (SP), General Injectables and Vaccines, Inc. (GIV), and GlaxoSmithKline (GSK) for the trivalent, inactivated influenza vaccine, FluZone[®], FluLaval[®], and Fluarix[®]; and MedImmune for the live, attenuated influenza vaccine, FluMist[®]. MedImmune FluMist[®] shipments will begin early August. The shipments of inactivated vaccines are expected to commence in September and finish by mid-December.
- c) Defense Contracting Supply-Philadelphia (DSCP) obtained 45% of DoD requirements as FluMist[®], 30% as FluLaval[®], and 9% as Fluarix[®]. The remaining doses are FluZone[®] products. Fluzone[®] vaccines are the only products currently FDA-approved for infants and children less than 5 years of age or 5-18 years of age with chronic medical conditions. FluZone[®] should be reserved for these specific pediatric populations.
- d) Due to the various influenza vaccine products available this season it is imperative that upmost care and attention is devoted to providing correct immunizations based on age and medical conditions and that recording of immunizations given is accurate.
- e) Air Force Medical Logistics (AFMLO) is responsible for ordering and distributing influenza vaccine for AFMS activities. AFMLO will notify units of the quantities

ordered and the document numbers being used. Additional quantities required must be coordinated with AFMSA/SGSLC, DSN: 343-4170, commercial (301) 619-4170. AFMLO website is: https://www.afml.ft-detrick.af.mil/afmlo/procurement/FLUMenu.cfm. National supply and epidemic levels may restrict vaccine availability.

- f) Do not use leftover vaccines from previous year's influenza immunization program for current year's program.
- g) DoD contracted vaccines
 - **FluMist**®—Live, attenuated influenza vaccine (LAIV)
 - (1) Description of FluMist®
 - (a) Cold-adapted, temperature-sensitive, live trivalent vaccine.
 - (b) Designed to stimulate an immune response that more closely resembles the body's response to a natural influenza infection.
 - (c) Stimulates local defenses in the nasal mucosa against influenza and promotes a systemic immune response.
 - (d) Contains attenuated live vaccine strains that are engineered not to cause systemic disease
 - (i) Attenuated: weakened so as not to cause influenza-like illness
 - (ii) Cold-adapted: replicates efficiently in the cooler temperatures of the nasopharynx
 - (iii)Temperature-sensitive: does not replicate efficiently in the warmer temperatures of the lower respiratory tract
 - (2) Indication
 - (a) FluMist[®] is indicated for active immunization for the prevention of disease caused by influenza A and B viruses in non-pregnant, healthy persons aged 5-49 years.
 - (b) Children 5-8 years old receiving vaccination with any influenza vaccine for the first time need two doses. Those who received only 1 dose in their first year of vaccination should receive 2 doses in the following year. FluMist[®] doses should be separated by ≥6 weeks.
 - (c) Persons 9-49 years old need only one initial dose.
 - (3) Contraindications for use of FluMist®
 - (a) FluMist must not be administered parenterally.
 - (b) Allergic history. Individuals with a history of hypersensitivity, especially anaphylactic reactions, to any component of FluMist[®], including eggs or egg products, should not receive FluMist[®].
 - (c) Aspirin therapy. FluMist is contraindicated in children and adolescents receiving aspirin therapy or aspirin-containing therapy because of the association of Reye syndrome with aspirin and wild-type influenza infection.

- (d) Guillain-Barre Syndrome. FluMist[®] should not be administered to individuals who have a history of Guillain-Barre syndrome.
- (e) Immune deficiency. FluMist[®] should not be administered to individuals with known or suspected immune deficiency diseases such as combined immunodeficiency, agammaglobulinemia, and thymic abnormalities and conditions such as human immunodeficiency virus infection, malignancy, leukemia, or lymphoma. FluMist[®] is also contraindicated in patients who may be immunosuppressed or have altered or compromised immune status as a consequence of treatment with systemic corticosteroids, alkylating drugs, antimetabolites, radiation, or other immunosuppressive therapies.
- (f) Respiratory disease. Warning. The safety of FluMist[®] in individuals with asthma or reactive airways disease has not been established. Therefore, FluMist[®] should not be administered to individuals with a history of asthma or reactive airway disease.
- (g) Pregnancy and breastfeeding. Animal studies have not been conducted with FluMist[®]. It is not known whether FluMist[®] can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. FluMist[®] should be given to a pregnant woman only if clearly needed. It is not known whether FluMist[®] is excreted in human milk. Therefore, as some viruses are excreted in human milk and additionally, because of the possibility of vaccine virus and the close proximity of a nursing infant and mother, caution should be exercised if FluMist[®] is administered to nursing mothers.
- (h) Other medical conditions. The safety of FluMist® in individuals with underlying medical conditions that may predispose them to severe disease following wild-type influenza infection has not been established. FluMist is not indicated for these individuals. High-risk individuals include, but are not limited to, adults and children with chronic disorders of the cardiovascular and pulmonary systems, including asthma; pregnant women; adults and children who required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes), renal dysfunction, or hemoglobinopathies; and adults and children with congenital or acquired immunosuppression caused by underlying disease or immunosuppressive therapy.
- (i) FluMist[®] is indicated for the active immunization of healthy children and adolescents 5-17 years of age, and healthy adults, 18-49 years of age, against influenza disease caused by influenza types A and B contained in the vaccine. FluMist[®] is not indicated for immunization of individuals less than 5 years of age, or 50 year of age and older, or for therapy of influenza, nor will it protect against infections and illnesses caused by infectious agents other than influenza A or B viruses.

(4) Precautions

(a) Prior to administration of FluMist[®], individuals or their parent/guardian should be asked about their current health status and their personal medical

- history, including immune status, to determine the existence of any contraindications to immunization with FluMist[®].
- (b) FluMist® recipients should avoid close contact (e.g., within the same household) with immunocompromised individuals for at least 21 days.
- (c) Epinephrine injection or comparable treatment must be readily available in the event of an acute anaphylactic reaction following vaccination.
- (d) Administration of FluMist[®] should be postponed until after the acute phase (at least 72 hours) of febrile and/or respiratory illnesses.
- (e) Based on the potential for interference between antiviral compounds and FluMist[®], it is advisable not to administer FluMist[®] until 48 hours after the cessation of antiviral therapy and that antiviral agents not be administered until two weeks after administration of FluMist[®] unless medically indicated.
- (f) Concurrent administration with other vaccines. The safety and immunogenicity of FluMist[®] when administered concurrently with other vaccines has not been determined. Healthcare providers should consider the risks and benefits of concurrent administration of FluMist[®] with other vaccines.
- (g) There is no data available regarding co-administration of FluMist® with other intranasal preparations, including steroids.
- (h) Aeromedical disposition policy following administration of this vaccine is the same as for injectable immunizations as outlined in the Aircrew Medication List policy letter dated 22 Sep 04. Symptoms such as runny nose, congestion, mild headache, sore throat, and fatigue or weakness may occur within the first 7 days. The presence and severity of these symptoms may require Duty Not Including Flying/Duty Not Including Controlling (DNIF/DNIC) action for some aircrew and special operational duty personnel. To minimize operational impact, it is recommended that no more than 50% of those eligible in each unit be administered the vaccine within any given week. The Chief of Aerospace Medicine for each base should work closely with flying and special operational duty commanders to devise a Flumist[®] immunization plan for these personnel.

(5) Adverse Events

- (a) In children, side effects can include runny nose, headache, vomiting, muscle aches, and fever.
- (b) In adults, side effects can include runny nose, headache, sore throat, and cough. Fever is not a common side effect in adults.
- (c) Other adverse events reported include nausea, rash, and hypersensitivity reactions (including anaphylaxis, facial edema, and urticaria).
- (6) Conditions of transportation, arrival, and storage
 - (i) FluMist[®] should arrive frozen.
 - (ii) The cold chain must be maintained when transporting FluMist[®].
 - (iii)FluMist[®] should be stored in a refrigerator between 2-8° C (35-46° F) upon receipt and until use before the expiration date.

(iv)DO NOT REFREEZE.

(v) For information regarding product storage and stability under conditions other than those recommended, call 1-877-FLUMIST. Recipients of overseas shipments should consult DSCP for questions related to enclosed "Temp Tales" monitors.

(7) Administration

- (a) Approximately 0.1 mL (i.e., half of the dose from a single FluMist[®] sprayer) is administered into each nostril while the recipient is in an upright position. Insert the tip of the sprayer just inside the nose and **rapidly** depress the plunger until the dose-divider clip stops the plunger. The dose-divider clip is removed from the sprayer to administer the second half of the doses (approximately 0.1ml) into the other nostril. The product should be extruded as a mist, not droplets!
- (b) Once FluMist® has been administered, the sprayer should be disposed in accordance with standard procedures for medical waste.

• Trivalent Inactivated Influenza Vaccine (TIV)

Inactivated influenza vaccines are FDA-approved for specific age groups. Follow package insert for use of influenza vaccines in the appropriate age groups. The two injectable influenza vaccines available for the 2006-07 season are:

- (a) FluLaval®—Influenza virus vaccine, USP Split Trivalent 0.5 ml doses, 5 ml vial; for immunizing persons **18 years of age and older**.
- (b) Fluarix[®] —Influenza virus vaccine, USP Split Trivalent 0.5 ml single-dose prefilled disposable Tip-Lock[®] syringe for immunizing presons **18 years of age and older**.
- (c) FluZone[®] —Influenza virus vaccine, USP Split Trivalent 0.25 and 0.5 ml doses, 5 ml vial; for immunizing persons 6 months of age and older. RESERVE THIS PRODUCT FOR USE IN PATIENTS UNDER 18 YEARS OF AGE until their needs are adequately served.
- (d) FluZone[®] —Influenza virus vaccine, USP Trivalent Syringe-Needle Unit 10 Split Virus, Thimerosal/Preservative-free: **0.25 ml** dose for use in **infants** aged **6-35 months**.
- **Fluarix**®—Trivalent Inactivated Influenza Vaccine (TIV).
 - (1) Indication
 - a) Trivalent inactivated influenza vaccine, Fluarix, is indicated for active immunization of adults (18 years of age and older) against diseases caused by influenza virus types A and B contained in the vaccine.
 - b) The Advisory Committee on Immunization Practices has issued recommendations regarding the use of the inactivated influenza virus vaccine.
 - c) Fluarix® is not indicated for use in children.
 - (2) Vaccine arrival, storage, and transportation:

- a) Fluarix® should not have been frozen during transportation. If the enclosed temperature monitor's indicator light is red, do not issue to users until serviceability is confirmed by the "Temp Tales" monitor at the Defense Supply Center Philadelphia (DSCP). Follow indicator instructions enclosed with each shipment.
- b) Refrigerate Fluarix[®] immediately on arrival and store at 2-8° Centigrade (35-45° F). Do not freeze. Vaccine that has been frozen must be discarded. Contact DSCP for instructions prior to doing so. Store in the original package to protect from light.
- (a) Do not put Fluarix® vaccine directly on ice during local transport. Place cold packs in a suitable cooler and let the temperature stabilize for 5-10 minutes. (The manufacturer's recommendation is that 2° to 8° C is best for transporting vaccine). Place vaccine in the container only after the temperature is stable. Check the temperature with a thermometer.

(3) Vaccine instructions.

- (a) Draw and administer vaccine IAW the Advisory Committee on Immunization Practices (ACIP) guidelines.
- (b) Shake vials vigorously before withdrawing each dose. Shake prefilled syringes well before administering.
- (c) The dose of Fluarix[®] is a single 0.5 mL injection in adults administered intramuscularly, preferably in the region of the deltoid muscle. A needle of ≥ 1 inch is preferred because needles < 1 inch might be of insufficient length to penetrate muscle tissue in certain adults.
- (d) Do not inject intravenously. Avoid injection in areas where there may be a major nerve trunk.
- (e) Shelf life: The vaccine is good until the expiration date listed on vaccine vial or package insert as long as it is properly stored and not contaminated.

(4) Precautions

- (a) Do not administer by intravascular injection.
- (b) Prior to administration of Fluarix[®], the patient's current health status and medical history should be reviewed.
- (c) Appropriate medical treatment and supervision should be readily available for immediate use in case of a rare anaphylactic reaction following the administration of the vaccine. Epinephrine injection (1:1,000) and other appropriate agents used for the control of immediate allergic reactions must be immediately available.
- (d) A separate, sterile syringe and needle or a sterile disposable unit should be used for each patient to prevent transmission of other infectious agenst from person to person. Needles should be disposed of properly and should not be recapped.

(5) Contraindications

(a) Fluarix® should not be administered to anyone with known systemic hypersensitivity reactions to egg proteins, to chicken proteins, or to any

- component of Fluarix® or who has had a life-threatening reaction to previous administration of any influenza vaccine.
- (b) Immunization should be delayed in a patient with an active neurologic disorder, but should be considered when the disease process has been stabilized.
- (c) If Guillain-Barre syndrome has occurred within 6 weeks of receipt of prior influenza vaccine, the decision to give Fluarix[®] or any influenza vaccine should be based on careful consideration of the potential benefits and possible risks.
- (d) Fluarix® should not be given to individuals with bleeding disorders such as hemophilia or thrombocytopenia, or to persons on anticoagulant therapy unless the potential benefit clearly outweighs the risk of administration.
- (e) Vaccination with Fluarix[®] may not protect 100% of susceptible individuals.
- (f) The tip cap and the rubber plunger of the needlesless prefilled syringes contain dry natural latex rubber that may cause allergic reactions in latex sensitive individuals.
- (g) The ACIP has published guidelines for vaccination of persons with recent or acute illness (www.cdc.gov).
- (h) Pregnancy: Animal studies have not been conducted with Fluarix[®]. It is not known whether Fluarix[®] can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Fluarix[®] should be given to a pregnant woman only if clearly needed. The ACIP has issued recommendations regarding the use of the influenza virus vaccine in pregnant women.
- (i) Nurshing Mothers: It is not known whether Fluarix[®] is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Fluarix[®] is administered to a nursing woman. The ACIP has issued recommendations regarding the use of the influenza vaccine in nursing mothers.
- (i) Pediatric Use: Fluarix[®] is not indicated for use in children.
- FluLaval®—Trivalent Inactivated Influenza Vaccine (TIV).
 - (1) Indication
 - (a) FluLaval[®] is an influenza virus vaccine indicated for active immunization of adults 18 years of age and older against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.
 - (b) FluLaval[®] is not indicated for use in children.
 - (2) Vaccine arrival, storage, and transportation:
 - (a) FluLaval[®] is supplied in a 5-ml multi-dose vial containing ten 0.5-ml doses. Once entered, the multi-dose vial should be discarded after 28 days.
 - (b) Store FluLaval refrigerated between 2° and 8° C (36° and 46° F.).
 - (c) **Do not freeze.** Discard if the vaccine has been frozen.
 - (d) Store in the original package to protect from light.

- (e) FluLaval® vaccine should not have been frozen during transportation. If the enclosed temperature monitor's indicator light is red, do not issue to users until serviceability is confirmed by the "Temp Tales" monitor at the Defense Supply Center Philadelphia (DSCP). Follow indicator instructions enclosed with each shipment.
- (f) Do not put vaccine directly on ice during local transport. Place cold packs in a suitable cooler and let the temperature stabilize for 5-10 minutes. Check the temperature with a thermometer. Place vaccine in the container only after the temperature is stable.
- (g) The vial stopper does not contain latex.
- (h) Thimerosal, a mercury derivative, is added as a preservative. Each 0.5mL dose contains 25 mcg mercury.

(3) Vaccine instructions.

- (a) FluLaval should be administered as a single 0.5-ml injection by the intramuscular route preferably in the region of the deltoid muscle of the upper arm
- (b) The vaccine should not be injected in the gluteal area or areas where there may be a major nerve trunk. A needle of ≥1 inch is preferred because needles <1 inch might be of insufficient length to penetrate muscle in certain adults.
- (c) Before injection, the skin over the site to be injected should be cleaned with a suitable germicide.
- (d) After insertion of the needle, aspirate to ensure that the needle has not entered a blood vessel.

(4) Precautions

- (a) If Guillain-Barré syndrome has occurred within 6 weeks of receipt of prior influenza vaccine, the decision to give FluLaval® should be based on careful consideration of the potential benefits and risks.
- (b) Individuals with bleeding disorders or receiving anticoagulants are at risk of hematoma formation following intramuscular administration. Take steps to control the risk of hematoma following the injection in these persons.
- (c) Immunocompromised persons may have a reduced immune response to FluLaval[®].

(5) Contraindications

- (a) Known systemic hypersensitivity reactions to egg proteins, or any other component of FluLaval[®].
- (b) Life-threatening reaction to previous influenza vaccination.
- (c) Delay immunization in a patient with an acute evolving, neurologic disorder.

(6) Adverse Reactions

- (a) Most common ($\geq 10\%$) local adverse events were pain, redness, and/or swelling at the injection site.
- (b) Most common (≥ 10%) systemic adverse events were headache, fatigue, myalgia, low- grade fever, and malaise.

(c) To report SUSPECTED ADVERSE REACTIONS, contact GlaxoSmithKline at 1-888-825-5249 or VAERS at 1-800-822-7967 and www.vaers.hhs.gov.

(7) Use in Specific Populations

- (a) Safety and effectiveness of FluLaval[®] have not been established in pregnant women and children. Category C. Animal reproduction studies have not been conducted with FluLaval[®]. It is also not known whether FluLaval[®] can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. FluLaval[®] should be given to a pregnant woman only if clearly needed.
- (b) Nursing Mothers. It is not known whether FluLaval[®] is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when FluLaval[®] is administered to a nursing mother.
- (c) Pediatric Use. Safety and effectiveness of FluLaval® in pediatric patients have not been established.
- (d) Geriatric Use. Hemagglutination-inhibiting antibody responses were lower in geriatric subjects than younger subjects after administration of FluLaval[®].
- (e) Antibody responses were lower in geriatric subjects than in younger subjects.

(8) Drug Interactions

- (a) Do not mix with any other vaccine in the same syringe or vial.
- (b) May increase blood levels of warfarin, theophylline, and phenytoin.
- (c) Immunosuppressive therapies may reduce immune responses to FluLaval[®].

(9) Patient Counseling Information

- (a) Vaccine recipients and guardians should be informed by their healthcare provider of the potential benefits and risks of immunization with FluLaval[®]. When educating vaccine recipients and guardians regarding potential side effects, clinicians should emphasize that (1) FluLaval[®] contains non-infectious killed viruses and cannot cause influenza and (2) FluLaval[®] is intended to provide protection against illness due to influenza viruses only, and cannot provide protection against all respiratory illness.
- (b) Vaccine recipient or guardian should be given the Vaccine Information Statements, which are required by the National Childhood Vaccine Injury Act of 1986 to be given prior to immunization.
- (c) Vaccine recipients and guardians should be instructed that annual revaccination is recommended.

• FluZone®—Trivalent Inactivated Influenza Vaccine (TIV).

(1) Indication

- (a) Trivalent inactivated influenza vaccine is approved for persons aged \geq 6 months including those with high-risk conditions
- (2) Vaccine arrival, storage, and transportation:
 - (a) FluZone® vaccine should not have been frozen during transportation. If the enclosed temperature monitor's indicator light is red, do not issue to users

- until serviceability is confirmed by the "Temp Tales" monitor at the Defense Supply Center Philadelphia (DSCP). Follow indicator instructions enclosed with each shipment.
- (b) Refrigerate vaccine immediately on arrival and store at 2-8° Centigrade (35-45° Fahrenheit). Do not freeze.
- (c) Do not put vaccine directly on ice during local transport. Place cold packs in a suitable cooler and let the temperature stabilize for 5-10 minutes. Check the temperature with a thermometer. (The manufacturer's recommendation for transporting vaccine is 2-8° C.) Place vaccine in the container only after the temperature is stable.

(3) Vaccine instructions.

- (a) Draw and administer vaccine IAW the Advisory Committee on Immunization Practices (ACIP) guidelines.
- (b) Shake vials vigorously before withdrawing each dose. Shake prefilled syringes well before administering.
- (c) Shelf life: The vaccine is good until the expiration date listed on vaccine vial or package insert as long as it is properly stored and not contaminated.
- (4) Inactivated influenza vaccines are FDA-approved for specific age groups. Follow package insert for use of influenza vaccines in the appropriate age groups. The injectable influenza vaccines available for the 2006-07 season are:
 - (a) FluZone[®] —Influenza virus vaccine, USP Split Trivalent 0.25 and 0.5 ml doses 10 dose vial; for immunizing persons 6 months of age and older.
 - (b) FluZone®—Influenza virus vaccine, USP Trivalent Syringe-Needle Unit 10 Split Virus, Thimerasol/Preservative-free: **0.25 ml** dose, for immunizing persons **6-35 months of age.**
 - (c) Note: DSCP did not contract for the **0.5 ml** preloaded syringe dose of Thimerasol/Preservative-free vaccine pediatric dose for use in infants aged over 35 months. These may be available as a local purchase, NSN: 6505-01-530-1765.

(5) Precautions

- (a) Administer with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.
- (b) Use of influenza virus vaccine should be delayed during the course of any febrile respiratory illness or other active invection.
- (c) The stopper to the vial of influenza vaccine contains dry natural latex rubber that may cause allergic reactions. The syringe does not cotain latex of any kind.

(6) Contraindications

(a) Allergic history. Influenza vaccine should not be administered to persons with known anaphylactic hypersensitivity to eggs or to other components of the influenza vaccine without first consulting a physician (information on vaccine components can be found in package inserts). Persons who have had

hives or swelling of the lips or tongue, or who have experienced acute respiratory distress or collapse after eating eggs should consult a physician for appropriate evaluation to help determine if vaccine should be administered. Mild systemic reaction with fever, malaise, myalgia, and local redness at the injection site should not be considered to be an allergic reaction to influenza vaccine. These side effects are self-limiting and resolve quickly. Persons who have a history of anaphylactic hypersensitivity to vaccine components but who are also at high risk for complications from influenza may benefit from vaccine after appropriate allergy evaluation and, if necessary, desensitization. Protocols have been published for safely administering influenza vaccine to persons with egg allergies.

- (b) Current infections. Persons with moderate to severe acute infectious illnesses normally should not be vaccinated until their symptoms have improved. However, minor illnesses with or without fever, particularly among children with minor upper respiratory tract infection or allergic rhinitis, do not contraindicate the use of influenza vaccine.
- (c) Pregnancy or Breastfeeding. Neither pregnancy nor breastfeeding is a contraindication to inactivated influenza immunization.
- (d) Neurologic disease and history of Guillain-Barre Syndrome (GBS). Whether influenza vaccination increases the risk for recurrence of GBS is unknown. Avoid vaccinating individuals known to have experienced GBS within 6 weeks after a previous influenza vaccination who are not at high risk for severe influenza complications. Physicians might consider using influenza antiviral chemoprophylaxis for these persons. For the majority of persons who have a history of GBS and are at high risk for severe complications from influenza the established benefits of influenza vaccination justify yearly vaccination. Immunization should be delayed in a patient with an active neurologic disorder but should be reconsidered when the disease process has been stabilized.
- (7) Side effects and adverse reactions: When educating patients regarding potential side effects it should be emphasized that inactivated influenza vaccine contains noninfectious, killed viruses which cannot cause influenza and that coincidental respiratory diseases unrelated to influenza vaccination can occur after vaccination.

 (a) Side effects:
 - (i) Local reactions (affecting 10-64% of patients) include soreness at the vaccination site and can last up to 2 days. These local reactions typically are mild and rarely interfere with the person's ability to conduct usual daily activities.
 - (ii) Systemic reactions including fever, malaise, myalgia, and other systemic symptoms may begin 6-12 hours after vaccination and can persist for 1-2 days. These symptoms most often affect persons who have had no prior exposure to the influenza virus antigens in the vaccine, e.g., young children.

- (iii)Immediate, presumably allergic, reactions (e.g., hives, angioedema, allergic asthma, and systemic anaphylaxis) occur rarely after influenza vaccination. These reactions probably result from hypersensitivity to certain vaccine components. The majority of reactions probably are caused by residual egg protein from the manufacturing process.
- (8) Pre-drawing vaccine may increase the chance of wastage or decrease potency. In certain circumstances where a single vaccine type is being used (e.g., a community influenza vaccination campaign), filling multiple syringes for immediate use can be considered.
 - (a) Care should be taken to ensure that the cold chain is maintained until the vaccine is administered.
 - (b) When the syringes are pre-filled, the type of vaccine, lot number, and date of filling must be carefully labeled on each syringe, and the doses should be administered as soon as possible after filling. Refer to manufacturer's recommendations in the package insert for detailed instructions.
- (9) Side effects and adverse reactions: When educating patients regarding potential side effects it should be emphasized that inactivated influenza vaccine contains noninfectious, killed viruses which cannot cause influenza and that coincidental respiratory diseases unrelated to influenza vaccination can occur after vaccination. Most events are mild and self-limited.
 - (a) Local reactions (affecting 10-64% of patients) include pain, redness, and swelling at the vaccination site and can last up to 2 days. These local reactions typically are mild and rarely interfere with the person's ability to conduct usual daily activities.
 - (b) Systemic reactions including fever, malaise, myalgia, fatigue, headache, shivering, and other systemic symptoms may begin 6-12 hours after vaccination and can persist for 1-2 days. These symptoms most often affect persons who have had no prior exposure to the influenza virus antigens in the vaccine, e.g., young children.
 - (c) Immediate, presumably allergic, reactions (e.g., hives, angioedema, allergic asthma, and systemic anaphylaxis) occur rarely after influenza vaccination. These reactions probably result from hypersensitivity to certain vaccine components. The majority of reactions probably are caused by residual egg protein from the manufacturing process.

FluMist[®]—live, attenuated influenza vaccine (LAIV)

Age Group	Vaccination Status	Dosage Schedule
Children age 5 years through 8 years	Not previous vaccinated or only 1 dose in first season	2 doses (0.2 mL each, 60 days apart)

Children age 5 years through 8 years	Previously vaccinated with 2 doses in first season	1 dose (0.2 mL) per season
Children and adults age 9 through 49 years	Not applicable	1 dose (0.2 mL) per season

Although either FluZone or FluMist may be used for the purpose of initial-year immunization, the two types of vaccine are not interchangeable. The child should receive the same type of vaccine for each of the two immunizations.

FluZone® — inactivated influenza vaccine

Age Group	Dosage	Number of Doses
6-35 months	0.25 mL	1 or 2*
3-8 years	0.50 mL	1 or 2*
≥ 9 years	0.50 mL	1

^{*} Two doses administered at least one month apart are recommended for children <9 years who are receiving influenza vaccine for the first time. If a child <9 years receiving vaccine for the first time does not receive a second dose of vaccine within the same season, 2 doses of vaccine should be administered the following season. Although either FluZone or FluMist may be used for the purpose of initial year immunization; they are not interchangeable. The child should receive the same type of vaccine for each immunization.

For adults and older children, the recommended site of vaccination is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh.

Fluarix[®]— inactivated influenza vaccine

Age Group	Dosage	Number of Doses
18 years and older	0.50 mL	1

For adults, the recommended site of vaccination is the deltoid muscle

FluLaval®— inactivated influenza vaccine

Age Group	Dosage	Number of Doses
18 years and older	0.50 mL	1

For adults, the recommended site of vaccination is the deltoid muscle

4) Timing of Annual Influenza Immunization.

a) Antibodies sufficient to achieve protection against influenza infection develop within two weeks of vaccination. Influenza vaccinations should begin as early in the season as is possible. Begin mass immunization programs as soon as adequate quantities of the

- vaccine are available. Influenza activity usually peaks in the United States between late December and early March. During the past 23 flu seasons, months with the heaviest flu activity (peak months) occurred in December in 4 years (17%), January in 5 years (22%), February in 9 years (43%), and March in 4 years (17%). Vaccination of susceptible individuals through June may be beneficial as influenza infection continues throughout the year.
- b) When production and projected distribution schedules allow for sufficient supply of influenza vaccine, no prioritization is necessary. Vaccination of all military members should be completed within one month of receipt of sufficient vaccine supplies. FluMist[®], the preferred vaccine for appropriate Service members, is expected to be available by late September, 2007. Current contracts from all manufacturers provide delivery of 20-40% of DoD requirements by the end of September and October with the remaining doses to be delivered by the end of November.
- c) Efforts to vaccinate healthy persons who wish to decrease their risk for influenza infection should primarily utilize FluMist[®]. Vaccination of these individuals with injectable vaccine should be deferred until the target populations have had ample opportunity to receive the vaccine. FluZone[®] products should be reserved for the appropriate pediatric populations.
- d) Other Prioritization Plans.
 - "It is DoD policy that the general recommendations of the US Public Health Service, as promulgated by the Centers for Disease Control (CDC) Immunization Practices Advisory Committee (ACIP) and published in CDC's Morbidity and Mortality Weekly Report (MMWR) shall be followed." DoDI 6205.2
 - Vaccination tiering should only be used when there are issues of vaccine supply.
 - In event of a severe influenza epidemic, extreme vaccine shortage, or unforeseen distribution delays, target populations will be prioritized in accordance with Assistant Secretary of Defense, Health Affairs policy guidance. If necessary, more specific priority alterations will be given at the direction of AFMOA/SGPP.
- e) Deployers or travelers who were not vaccinated during the preceding fall or winter and are deploying/traveling to the Southern Hemisphere during April-September or to the tropics in organized groups any time of the year should receive influenza vaccine prior to travel. Caution: FDA-approved influenza vaccines are not available at all times during the year; follow expiration dates on the package or bottle.
- 5) Target Groups and Specific Instructions for Influenza Immunization: Follow AFJI 48-110 and the most recent ACIP guidance for instructions on vaccine administration for specific age groups and recommendations on targeting certain high-risk groups. When there are no anticipated vaccine shortages or delays, influenza vaccination should proceed in parallel for military members, medically high-risk individuals, and other target populations through mass campaigns as soon as adequate supplies of appropriate vaccine is available.
 - a) Target Groups and Goals. Improve annual influenza vaccination coverage for the following groups:
 - Mandatory: All AD and ARC members in accordance with AFJI 48-110.

- Beneficiaries aged \geq 65 years. Achieve Healthy People 2010 Target of 90%.
- Persons aged 2—64 years with underlying chronic medical conditions. Achieve Healthy People 2010 Target of 60% for high-risk adults (aged 18-64 years).
- All women who will be pregnant during the influenza season. Vaccination with injectable vaccine can occur in any trimester. Pregnancy is a contraindication to the use of FluMist.
- Beneficiaries aged \geq 50 to 64 years
- All children from 6 months up to 5 years of age
- Household contacts and out-of-home caregivers of infants <6 months
- Household contacts and out-of-home caregivers of infants and children from 6 months to 5 years
- Residents of nursing homes and long-term care facilities
- Children aged 6 months—18 years on chronic aspirin therapy
- Healthcare workers involved in direct patient care

ACIP GUIDELINE (29 June 2007)

Target Groups for Vaccination

Persons for whom annual vaccination is recommended

Annual vaccination against influenza is recommended for

- All persons, including school-aged children, who want to reduce the risk of becoming ill with influenza or of transmitting influenza to others
- All children aged 6-59 months (i.e., 6 months-4 years)
- All persons \geq 50 years
- Children and adolescents (aged 6 months-18 years) receiving longterm aspirin therapy who therefore might be at risk for experiencing Reye's syndrome after influenza virus infection
- Women who will be pregnant during the influenza season
- Adults and children who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological or metabolic disorders (including diabetes mellitus)
- Adults and children who have immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus)
- Adults and children who have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function of the handling of respiratory secretions or that can increase the risk for aspiration

- Residents of nursing homes and other chronic-care facilities
- Health-care personnel
- Healthy household contacts (including children) and caregivers of children aged <5 years and adults aged ≥50 years, with particular emphasis on vaccinating contacts of children < 6 months
- Healthy household contact (including children) and caregivers of persons with medical conditions that put them at higher risk for severe complications from influenza

Persons Infected with HIV

Because influenza can result in serious illness and because vaccination with inactivated influenza vaccine can result in the production of protective antibody titers, vaccination will benefit HIV-infected persons, including HIV-infected pregnant women. FluMist is contra-indicated, however.

Persons Who Can Transmit Influenza to Those at High Risk

- o health-care workers
- o employees of assisted living and other residences for persons in groups at high risk
- o persons who provide home care to persons in groups at high risk
- household contacts (including children) of persons in groups at high risk.
- o household contacts (anyone who spends a significant amount of time in the home) and out-of-home caregivers of children 0-59 months old.
- Healthy persons aged 5—49 years who are close contacts of severely immuno-suppressed persons should receive inactivated influenza vaccine rather than the attenuated, live vaccine (FluMist[®]).

Health-Care Workers

All health-care workers should be vaccinated against influenza annually

Pregnant Women

Women who will be pregnant any time during the influenza season should be vaccinated

Persons Aged 50--64 Years

Vaccination is recommended for persons aged 50--64 years because this group has an increased prevalence of persons with high-risk conditions

Healthy Young Children

- Because children aged 6—59 months are at substantially increased risk for influenza-related hospitalizations, ACIP recommends vaccination of all children in this age group
- o Beginning March 2003, the Vaccines for Children (VFC) program was expanded to include influenza vaccine coverage

General Population

- o In addition to the groups for which annual influenza vaccination is recommended, physicians should administer influenza vaccine to any person who wishes to reduce the likelihood of becoming ill with influenza or transmitting influenza to others should they become infected (the vaccine can be administered to children aged ≥ 6 months), depending on vaccine availability
- Persons who provide essential community services should be considered for vaccination to minimize disruption of essential activities during influenza outbreaks.
- o Students or other persons in institutional settings (e.g., those who reside in dormitories) should be encouraged to receive vaccine to minimize the disruption of routine activities during epidemics.
- o Live, attenuated FluMist® should be used whenever not otherwise contraindicated in the healthy, non-pregnant 5-49 year old populations

b) Implement strategies to improve vaccination rates.

- Reminder/recall systems to target beneficiaries at increased risk for complications from influenza
- Standing orders or standard operating procedures. Examples include pre-written
 vaccine orders for adults or other high-risk beneficiaries; provide hospitalized patients
 flu vaccine prior to discharge; remind pregnant women to receive vaccine during
 routine prenatal care.
- Assess vaccination coverage rates. MTFs should regularly assess their vaccine coverage rates throughout the influenza season and attempt to improve coverage for military members, enrolled infants and children 6-59 months of age, enrolled beneficiaries aged ≥ 50 years and other medically high-risk individuals. Information on vaccine completion rates for certain groups is updated regularly and available at the Air Force Corporate Health Information Processing Service (AFCHIPS) website.
- Self-identification questionnaires and clinic posters. MTFs should post materials in patient- care areas, waiting rooms, prenatal and immunization clinics, and other areas likely to target high-risk groups. These are available at http://www.cdc.gov/flu/professionals/patiented.htm.
- Employ other patient-oriented and community-based approaches to reach target populations

- Use the opportunity to evaluate servicemember and beneficiary shot records to update other immunizations wherever possible
- c) The Population Health Support Division (PHSD) provides MTFs' patient-enrollment data through the AF Population Health Portal (AFPHP). Primary care managers should facilitate identification of target patients for reminder recall. MTFs can contact PHSD at DSN 240-8190, comm. (210) 536-8190 email: phsohelpdesk@brooks.af.mil for information about accessing the AFPHP.
- d) Persons with certain underlying medical conditions will also benefit from pneumococcal vaccination if not previously vaccinated. MTFs should identify eligible individuals and use opportunity during influenza campaign to ensure that these individuals are up-to-date on pneumococcal vaccination, in accordance with ACIP recommendations or http://www.cdc.gov/mmwr/preview/mmwrhtml/00047135.htm. The *Healthy People* 2010 target for one-time pneumococcal vaccination for adults aged ≥ 65 years is 90%.
- e) Influenza vaccination for federal civilian employees, foreign nationals or other non-DoD individuals. See AFJI 48-110 for guidance.
- f) MTFs should ensure communication of plan and local strategies to all involved parties. Public affairs resources are available through CDC at http://www.cdc.gov/flu.
- 6) **Documentation:** All vaccinations will be documented in Air Force Complete Immunization Tracking Application (AFCITA). Mass immunization and workplace vaccination campaign planning must consider this requirement for AD, Reserve Component, and DoD beneficiaries (e.g., automated methods on-site or manual lists at vaccination site compiled and used to update AFCITA). The AFCHIPS website provides base-level influenza vaccination completion data throughout influenza season and is available at https://www.afchips.brooks.af.mil/main.htm.

 Accurate documentation of Flu vaccines given during Flu vaccine programs continues to be a challenge. All influenza immunizations administered will be entered into AFCITA. MTF's are strongly encouraged to utilize the stand-alone capacity of AFCITA when giving

immunizations outside the MTF. Paper "sign-in rosters" are discouraged. If paper rosters

must be utilized, data must be entered into AFCITA within 24 hours.

- 7) Vaccine Information Statement (VIS) and Adverse Event Reporting (VAERS): The VIS on influenza vaccine, published by the CDC, should be made available and provided to any individual upon request. The VIS is available at http://www.cdc.gov/vaccines/pubs/vis/default.htm.
 - a) Reporting. Health-care professionals should promptly report all clinically significant adverse events after influenza vaccination of children to VAERS, even if the health-care professional is not certain that the vaccine caused the event. All vaccine-related adverse events must be reported through the Vaccine Adverse Event Reporting System. The

Institute of Medicine has specifically recommended reporting of potential neurologic complications (e.g., demyelinating disorders such as Guillain-Barre Syndrome), although no evidence exists of a causal relationship between influenza vaccine and neurologic disorders in children. The VAERS form is available at http://vaers.hhs.gov. The form must be submitted to the Food and Drug Administration (FDA) and it may be transmitted electronically.

- b) Vaccine adverse events are reportable events and must also be submitted to the Air Force Institute for Operational Health (AFIOH), Epidemiology Services Branch preferably by fax at DSN 240-6841 or (210) 536-6841. VAERS reporting will be integrated into AFRESS once the web-based version is complete.
- c) Incidents that are considered life-threatening or that result in death must be reported to AFIOH within 24 hours. Other reports of vaccine adverse reactions or events should be faxed or mailed within 7 days of occurrence.

8) ANG and AFRES Activities:

- a) Air National Guard (ANG) Activities: For the 2007-2008 influenza season, the ANG is requisitioning all vaccine requirements thru FM4425, 79 MDG, Andrews AFB. ANG Wing requirements are based on data in AFCITA and have been calculated at the MAJCOM level. Each ANG Wing's and its GSU's vaccine requisition will have a unique document number linked to the local ANG MDG's FY DODAAC. Delivery will be made to the ANG MDG. Questions should be directed to MSgt Piers Heriz-Smith, DSN 278-8577, Piers.Heriz-Smith@ang.af.mil.
- b) Air Force Reserve Command (AFRC) Activities: AFRC activities should contact the host base (FM) account for their requirements. Contact HQ AFRC/SGPH at DSN 497-2398 or commercial at 478-327-2398 if further instruction is necessary. Individual Mobilization Augmentees will be immunized by their supporting AD MTF and should be included in requirements for the MTF.

9) **Contact information**:

- a) Influenza vaccine supply, delivery, shortage and availability issues: Contact AFMSA/SGSLC, Fort Detrick, MD. DSN 343-4170 or (301) 619-4170, fax: DSN 343-6844 or (301) 619-6844, e-mail: sgslc@ft-detrick.af.mil
- b) **Policy and prioritization**: Contact William Meyer, Lt Col, AFMSA/SGPP, 110 Luke Ave, Room 405, Bolling AFB, DC 20032-7050, DSN 297-4268 or (202) 767-4268, e-mail: william.meyer@pentagon.af.mil.
- c) VAERS: Contact AFIOH Epidemiology Services and Risk Assessment Division at 2513 Kennedy Circle, Brooks City Base, Texas 78235-5116 at DSN 240-3471 or (210) 536-3471, fax DSN 240-6841. https://gumbo.brooks.af.mil/pestilence/VAERS/VAERS.cfm. E-mail: vaers@brooks.af.mil

10) References:

- a) AFJI 48-110 Immunizations and Chemoprophylaxis, 29 Sep 2006
- b) Assistant Secretary of Defense, Health Affairs policy documents available at: http://www.ha.osd.mil/policies/default.cfm
- c) Centers for Disease Control and Prevention (CDC) influenza home page contains provider's information, supply concerns and updates, public affairs and media materials, and patient education materials. http://www.cdc.gov/flu/professionals/patiented.htm.
- d) Prevention and Control of Influenza, Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR June 29, 2007 / 56(Early Release);1-54. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr56e629a1.htm.
- e) Morbidity and Mortality Weekly Report, Prevention of Pneumococcal Disease: Recommendations of the Advisory Committee on Immunization Practices. Volume 46, Number RR-8, 4 April 1997.
 - http://www.cdc.gov/mmwr/preview/mmwrhtml/00047135.htm.
- f) Morbidity and Mortality Weekly Report, Use of Standing Orders Programs to Increase Adult Vaccination Rates. Volume 49, RR-01, 24 March 00. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4901a2.htm.
- g) Morbidity and Mortality Weekly Report, Notice to Readers, Facilitating Influenza and Pneumococcal Vaccination through Standing Orders Programs. Volume 52, Number 4, 31 January 2003, pp.68-69. http://www.cdc.gov/mmwr/PDF/wk/mm5204.pdf
- h) Healthy People 2010. U.S. Department of Health and Human Services, 2000. www.health.gov/healthypeople/document/tableofcontents.htm.
- i) Standards for Adult Immunization Practices. Poland, GA et al. *American Journal of Preventive Medicine* 2003; Vol 25, Number 2.
- j) Recommended Childhood and Adolescent Immunization Schedule: United States, 2007. http://www.cdc.gov/nip/recs/child-schedule.htm.
- k) DoD Worldwide Influenza Surveillance Program AFIOH/RSRH web page. https://gumbo.brooks.af.mil/pestilence/Influenza/
- l) DoDI 6205.2, 9 Oct 1986. Immunization Practices. http://www.vaccines.mil/documents/714ImmReq.pdf
- m) DoDD 6205.02, 19 Sep 2006. Policy and Program for Immunizations to Protect the Health of Service Members and Military Beneficiaries. http://www.vaccines.mil/documents/973Policy620502p.pdf
- n) National Influenza Vaccine Summit Newsletter. http://www.ama-assn.org/go/influenzasummit